

**WE CLAIM:**

- 1 1. An oral pharmaceutical composition comprising:
  - 2 a) nateglinide or pharmaceutically acceptable salts thereof; and
  - 3 b) a water-soluble filler at a concentration range of 50-70% w/w of the
  - 4 composition.
- 1 2. The oral pharmaceutical composition according to claim 1, wherein at least 70%  
2 by weight of the nateglinide is released within 45 minutes in 1000 ml, 0.01 N HCl, with  
3 0.5% SLS (pH=1.2), using USP apparatus – II, at 50 rpm.
- 1 3. The oral pharmaceutical composition according to claim 1, wherein the water-  
2 soluble filler comprises one or more of lactose, white sugar, sucrose, glucose, sorbitol and  
3 mixtures thereof.
- 1 4. The oral pharmaceutical composition according to claim 3, wherein the water-  
2 soluble filler comprises lactose.
- 1 5. The oral pharmaceutical composition according to claim 1, further comprising one  
2 or more pharmaceutically acceptable excipients.
- 1 6. The oral pharmaceutical composition according to claim 5, wherein the one or  
2 more pharmaceutically acceptable excipients comprise one or more of binders,  
3 disintegrants, lubricants, and coloring and flavoring agents.
- 1 7. The oral pharmaceutical composition according to claim 6, wherein the binder  
2 comprises one or more of methyl cellulose, hydroxypropyl cellulose, hydroxy propyl  
3 methyl cellulose, povidone, gelatin, gum Arabic, ethyl cellulose, polyvinyl alcohol,  
4 pullulan, pregelatinized starch, agar, tragacanth, sodium alginate, propylene glycol, and  
5 mixtures thereof.
- 1 8. The oral pharmaceutical composition according to claim 7, wherein the binder  
2 comprises povidone.
- 1 9. The oral pharmaceutical composition according to claim 6, wherein the  
2 disintegrant comprises one or more of starch, croscarmellose sodium, crospovidone,  
3 sodium starch glycolate, polacrillin potassium and mixtures thereof.
- 1 10. The oral pharmaceutical composition according to claim 9, wherein the  
2 disintegrant comprises croscarmellose sodium.

- 1 11. The oral pharmaceutical composition according to claim 6, wherein the lubricant  
2 comprises one or more of colloidal anhydrous silica, stearic acid, magnesium stearate,  
3 calcium stearate, talc, hydrogenated castor oil, sucrose esters of fatty acids,  
4 microcrystalline wax, yellow beeswax, and white beeswax.
- 1 12. The oral pharmaceutical composition according to claim 11, wherein the lubricant  
2 comprises magnesium stearate.
- 1 13. The oral pharmaceutical composition according to claim 1, wherein the  
2 pharmaceutical composition comprises a tablet or capsule.
- 1 14. The oral pharmaceutical composition according to claim 13, wherein the tablet is  
2 coated with one or more functional and/or non-functional layers.
- 1 15. The oral pharmaceutical composition according to claim 1, further comprising one  
2 or more channeling agents.
- 1 16. The oral pharmaceutical composition according to claim 15, wherein the  
2 channeling agent comprises one or more of a sugar, a salt or a sugar alcohol, or  
3 combinations thereof.
- 1 17. The oral pharmaceutical composition according to claim 16, wherein the sugar  
2 comprises one or more of compressible sugar, glucose, and mannose.
- 1 18. The oral pharmaceutical composition according to claim 16, wherein the salt  
2 comprises one or more of sodium chloride, and potassium chloride.
- 1 19. The oral pharmaceutical composition according to claim 16, wherein the sugar  
2 alcohol comprises one or more of mannitol, sorbitol, xylitol, erythritol, lactitol, and  
3 maltitol.
- 1 20. The oral pharmaceutical composition according to claim 15, wherein the  
2 channeling agent comprises compressible sugar.
- 1 21. The oral pharmaceutical composition according to claim 15, wherein the  
2 channeling agent comprises sodium chloride.
- 1 22. A process for preparation of an oral pharmaceutical composition of nateglinide, the  
2 process comprising:  
3 a) blending nateglinide, disintegrant, and a water soluble filler to  
4 form a blend;

- 5                   b) granulating the blend with a binder solution;  
6                   c) drying and sizing the granules; and  
7                   d) lubricating and compressing the lubricated granules to form an  
8                   oral pharmaceutical composition, wherein the water soluble filler  
9                   is present at a concentration of 50% to 70% w/w of the oral  
10                  pharmaceutical composition.
- 1   23.    The process according to claim 22, further comprising blending a channeling agent  
2   with the nateglinide, disintegrant, and water soluble filler to form the blend.
- 1   24.    The process according to claim 22, wherein the granulation comprises wet  
2   granulation or dry granulation.
- 1   25.    The process according to claim 22, wherein the binder solution comprises a binder  
2   and a solvent.
- 1   26.    The process according to claim 25, wherein the solvent comprises one or more of  
2   methylene chloride, isopropyl alcohol, acetone, methanol, ethanol, and water.
- 1   27.    The process according to claim 22, wherein the blend further comprises one or  
2   more pharmaceutically acceptable excipients.
- 1   28.    The process according to claim 22, wherein the pharmaceutically acceptable  
2   excipients comprise one or more of binders, disintegrants, lubricants, coloring and  
3   flavoring agents.
- 1   29.    A method for the treatment of metabolic disorders, type 2 diabetes mellitus, or a  
2   disease or condition associated with diabetes mellitus, the method comprising  
3   administering to a patient in need thereof a pharmaceutical composition comprising:  
4                  a) nateglinide or pharmaceutically acceptable salts thereof; and  
5                  b) a water-soluble filler at a concentration range of 50-70% w/w of the  
6                  composition.
- 1   30.    The method according to claim 29, wherein the pharmaceutical composition  
2   administered further comprises a channeling agent.
- 1   31.    The method according to claim 29, wherein at least 70% by weight of the  
2   nateglinide is released within 45 minutes in 1000 ml, 0.01 N HCl, with 0.5% SLS (pH-  
3   1.2), using USP apparatus – II, at 50 rpm.